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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,679	04/16/2004	Ganesaratnam K. Balendiran	54435.8003.US01	9599

34055 7590 08/20/2007

PERKINS COIE LLP
POST OFFICE BOX 1208
SEATTLE, WA 98111-1208

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
08/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,679	BALENDIRAN, GANESARATNAM K.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-14 ARE PRESENTED FOR EXAMINATION

Applicant's amendment filed 8/13/2007 has been received and entered into the application. Accordingly, claims 6-10 have been amended and claim 14 has been added. Receipt is acknowledged of the replacement drawing sheets. The replacement drawings are sufficient to overcome the objection to the previously submitted drawings.

In view of the above amendments, the objection to claims 6, 8, and 10 has been overcome and thus is withdrawn. Also, the amendments and Applicants' remarks have overcome the rejections not reiterated herein from the previous office action. Such rejections are hereby withdrawn. The following rejections are either reiterated or newly applied and constitute the totality of issues remaining in the present application.

Claims 1-5 and 11-13 remain withdrawn from consideration as being drawn to non-elected subject matter.

Response to Arguments

Applicant's arguments, see response, filed August 13, 2007, with respect to claims 6 and 9-10 have been fully considered and are persuasive. The rejection of claims 6 and 9-10 under 35 U.S.C. 112, 1st Paragraph (Written Description) has been withdrawn.

Applicant's arguments filed August 13, 2007 have been fully considered but they fail to persuade the Examiner of an error in his determination that claims 6-10 are anticipated by the cited references. Applicants submit that the amendment to claim 6 wherein a method of inhibiting aldose reductase activity in a cell is now recited, rather than a method of treating a neoplasm, cannot be anticipated by the cited references because they do not disclose the ability

of fibrates to inhibit aldose reductase. However, the discovery of a new property of prior art methods does not render the instantly claimed methods patentable over the prior art. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In the instant case, all of the prior art references cited by the Examiner administer fibrates to cells. As such, inhibition of aldose reductase activity, while not recognized by the prior art, will *necessarily result* from administration of a fibrate to a cell as taught in the prior art. The method steps required by the instant claims (i.e., contacting a cell with a fibrate) are clearly and unequivocally taught by the prior art references. As such, the result being claimed (inhibition of aldose reductase activity) must have occurred when fibrates were administered to cells in the prior art. The fact that the prior art was not looking for such inhibition or did not recognize such inhibition had occurred is inconsequential to the present rejections. Accordingly, the claims are still deemed properly rejected as being anticipated by the cited prior references.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-10 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hirst *et al.* (Radiotherapy and Oncology, 1989, vol. 15, pages 55-61).

Hirst *et al.* teach that the antilipidemia drugs clofibrate and bezafibrate (instant claims 7 and 8) reduce the binding affinity of hemoglobin for oxygen and sensitize an experimental tumor (SCVII/St carcinoma) to radiation (Abstract; Figures 2, 3 and 4; Discussion). The drugs were administered at doses of 0.3 mmol/kg and 4.1 mmol/kg (pages 57-58).

The reference thus teaches administration of fibrates to an animal having a neoplasm in combination with radiation and therefore meets all of the limitations of the instant claims. With respect to the instantly claimed result of such administration of a fibrate (inhibition of aldose reductase activity), it is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently

described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Claims 6-9 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Scatena *et al.* (Cell Death and Differentiation, 1999, vol. 6, pages 781-787).

Scatena *et al.* administered bezafibrate and gemfibrozil to the human leukemia-dreived cell lines HL-60, U-937 and K-562 (Abstract). The results show that these fibrates induce differentiation and significantly alter cell cycle distributions (Abstract; Figures 1-6).

The reference thus teaches contacting a neoplasm cell with a fibrate thereby meeting all limitations of the instant claims. With respect to the instantly claimed result of such administration of a fibrate (inhibition of aldose reductase activity), it is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a

prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Claims 6, 8-10 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Calais *et al.* (Radiotherapy and Oncology, 1991, vol. 22, pages 99-103).

Calais *et al.* teach that the antilipidemia drug clofibrate (instant claim 8) sensitizes *in situ* a mouse carcinoma (CaNT) to radiation (Abstract; Figures 1-3; Table 1; Discussion). The authors conclude that clofibrate administration results in a significant increase in the sensitivity of a mouse carcinoma to radiation (page 103).

The reference thus teaches administration of a fibrate to an animal having a neoplasm in combination with radiation and therefore meets all of the limitations of the instant claims. With respect to the instantly claimed result of such administration of a fibrate (inhibition of aldose reductase activity), it is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a

characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Claims 6, 8-10 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cohen (Clin. Investig., 1993, vol. 71, pages 74-77).

Cohen teaches the use of gemfibrozil in a patient with chronic myelogenous leukemia to manage retinoid-induced hypertriglyceridemia (Abstract). The leukemia patient was being treated with chemotherapeutics (interferon-α and cytarabine) thus meeting the limitation of instant claim 10 (page 72). Due to a rise in triglycerides, the patient was given gemfibrozil orally twice daily in addition to his current chemotherapy (page 75).

The reference thus teaches administration of a fibrate and chemotherapy to a patient having a neoplasm (leukemia). With respect to the instantly claimed result of such administration of a fibrate (inhibition of aldose reductase activity), it is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664,

1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Claims 6-7, 9 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kawamura *et al.* (Anticancer Research, 1999, vol. 19, pages 4099-4104) (cited by Applicant in IDS filed 4/21/2005; Citation A49).

Kawamura *et al.* teach the administration of bezafibrate to mice having B16 melanoma (Abstract; page 4100). Bezafibrate reduced B16 melanoma-induced cachexia (Figure 2) and triglyceride levels (Figure 3). Further, bezafibrate reversed the decrease in glucose and increase in non-esterified fatty acids induced by B16 melanoma (Figure 3).

The reference thus teaches administration of a fibrate (bezafibrate) to animals having a melanoma neoplasia. With respect to the instantly claimed result of such administration of a fibrate (inhibition of aldose reductase activity), it is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior

art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
AU 1614

August 15, 2007

8/16/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER